1210 West 69th Terrace
Kansas City, Missouri 64113

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8 September 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: 21 CFR Parts 606 and 640
[Docket No. 98N-0673]
Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma

Sec. 606.151 Compatibility Testing

The proposed change still requires the use of serum, rather than allowing serum or plasma, for compatibility testing/pretransfusion testing. The use of plasma samples is not uncommon for these tests. The December 14, 1984 memorandum on Equivalent Methods for Compatibility Testing to All Registered Blood Establishments from the Office of Biologics Research and Review allows the use of plasma for the detection of unexpected alloantibodies. The *Standards of for Blood Banks and Transfusion Services* (19th Edition, 1999) of the American Association of Blood Banks allows use of either serum or plasma for compatibility testing. Given that many facilities now use IgG-specific antiglobulin reagents which do not detect bound complement, no advantage is gained by requiring the use of serum only. Use of plasma may be advantageous for some tests, such as gel technology, or for patients treated with heparin. It would be appropriate for Section 606.151 specifically to allow the use of plasma or serum. This would bring the section into agreement with recognized practice and current scientific thought and reduce confusion for both inspectors and transfusion services.

Sec. 640.5 Testing the Blood

This section continues to refer to tests for "the Rh variant D^u." The use of the term D^u is now considered archaic and inappropriate by blood group scientists. The term "weak D" is currently accepted and reflects the significant changes in anti-D reagents over the past years. This would be an appropriate time for the FDA to discontinue use of the D^u terminology, which is technically inappropriate and inconsistent with original usage and now serves only to add confusion.

Comments Submitted By:

Steven R Pierce
Steven R. Pierce, SBB(ASCP)

cc: Karen Shoos Lipton, American Association of Blood Banks
Jay E. Menitove, Chairman, Standards Committee, AABB

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98N-0673

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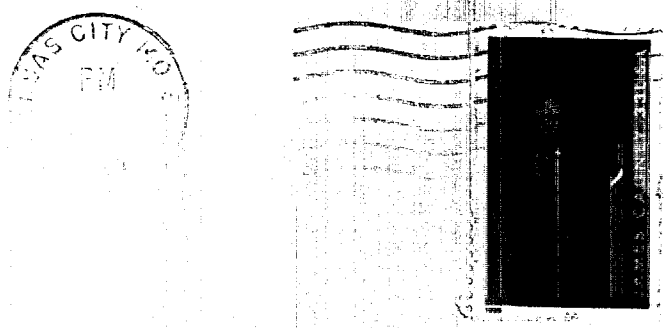

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